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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/761,180	01/20/2004	Jeffrey A. Hubbell	NOVCEL.3CPDDVC	2061

36647 7590 05/15/2006

NOVOCELL, INC.  
31 TECHNOLOGY DRIVE  
SUITE 100  
IRVINE, CA 92618

EXAMINER

BERMAN, SUSAN W

ART UNIT PAPER NUMBER

1711

DATE MAILED: 05/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/761,180	<b>Applicant(s)</b> HUBBELL ET AL.	
	<b>Examiner</b> Susan W. Berman	<b>Art Unit</b> 1711	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 March 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 129-135, 137, 138 and 148-181 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 129-135, 137, 138, 152-154, 156-162, 164-166 and 168-181 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 June 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

***Response to Amendment***

The Affidavit filed on 03/03/2006 under 37 CFR 1.131 has been considered but is ineffective to overcome the Soon-Shiong references.

The evidence submitted is insufficient to establish a reduction to practice of the invention in this country or a NAFTA or WTO member country prior to the effective date of the Soon-Shiong references.

The Affidavit of Jeffrey A. Hubbell filed 03/03/2006 has been considered. The evidence in the Affidavit show reduction to practice of a method comprising microencapsulating a cell in an alginate, coating the microcapsule with a photoinitiator, mixing the coated microcapsules into an aqueous macromer solution and polymerizing the gel to form macrocapsules. Exhibit A provides evidence of a gel formed from PEG as a macromer around an alginate-PLL-alginate microcapsule. Exhibit B provides evidence for use of ethyleosin and triethanol amine as cocatalyst and laser radiation at 514 nm. Exhibit B shows microencapsulation using an interfacial polymerization method for encapsulation of cells but does not include encapsulating the microcapsules in macrocapsules. Exhibit D provides evidence of living cells used as the cells in the microcapsules.

The Affidavit of Amarpreet S. Sawhney filed 03/03/2006 has been considered. Exhibit A provides evidence to show microencapsulation of islets in sodium alginate by an extrusion process. Exhibit B provides evidence of a method of introducing alginate-PLL microspheres into a solution containing ethyleosin. PEO acrylate solution is added and the solution is exposed to laser light (514 nm) to coat the microspheres with PEO gels.

The examiner does not find any evidence to show reduction to practice of a method comprising microencapsulating a cell, especially a living islet cell, followed by encapsulation of the microcapsules containing cells by macrocapsules, as set forth in claim 166 or 152. The method of claim 148 is considered to be supported by the evidence for reduction to practice before the effective filing date of Soon-Shiong et al. However, this claims has not been rejected over Soon-Shiong et al.

***Information Disclosure Statement***

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

***Terminal Disclaimer***

The terminal disclaimer filed on 10/26/2005 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US Patents 5,529,914; 5,858,746; 5,801,033 and 5,843,743 has been reviewed and is accepted. The terminal disclaimer has been recorded.

The terminal disclaimer includes US Patent no. 6,253,870; however, this is an incorrect patent no and should be US Patent 6,258,870. Correction is required.

***Specification***

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered submitted claim 1 has been renumbered claim 166 and newly submitted misnumbered claims 139-153 have been renumbered claims 167-181, according to Rule 1.126. Applicant

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filed an amendment 11/15/2005 canceling claims 1-128, 136 and 139-147. Claims pending are claims 129-135, 137 and 139, as amended 03/03/2006, claims 148-165, as submitted 11/15/2005 and claims 166-181, renumbered claims 1 and 139-153 submitted 03/03/2006.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 168-181 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the method set forth in claim 166, does not reasonably provide enablement for the method of claim 166 wherein step b is eliminated and step c is modified as set forth in claim 166. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 129, 134, 135, 137, 138 and 160 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims depend from a canceled claim and should be rewritten to depend from claim 166 (claim 1 renumbered claim 166 under Rule 1.126). With respect to claim 160, there is no antecedent basis in claim 152 for the recitation of geometric shapes. Claim 152 recites droplets.

***Claim Rejections - 35 USC § 102/103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 166, 129-135, 137, 138, 167, 152-154, 156-162 and 164-165 are rejected under 35 U.S.C. 102(e) as being anticipated by Soon-Shiong et al (5,700,848 or 5,705,270 or 5,846,530). See the Abstract and Examples 16-18 in US '848. Soon-Shiong teaches that the disclosed macrocapsules may contain cells that are encapsulated within microcapsules (column 9, lines 22-24, Example 26). With respect to claim 130, Soon-Shiong teaches poly(ethylene glycol), poly(amino acids), polysaccharides and proteins. Coextrusion is taught in Examples 16, 20 and 26. An accelerator to increase the rate of polymerization is taught in column 7, lines 37-49. With respect to claim 131, Soon-Shiong et al do not teach PEG tetraacrylate. However, the claim, as written, does not limit the macromer to being PEG tetraacrylate, it merely states that the PEG in the Markush group is PEG tetraacrylate.

Claims 166, 129-135, 137, 138, 167, 152-154, 156-162 and 164-165 are rejected under 35 U.S.C. 102(e) as being anticipated by Soon-Shiong et al (5,545,423 or 5,759,578 or 5,788,988 or 5,879,709). See the Abstract, column 7, line 43, to column 8, line 14, column 8, line 37, to column 9, line 14, column 11, line 64, to column 12, line 32, and Examples 5, 6 and 7 in US '423. Soon-Shiong teaches a method of microencapsulating cells such as islets and then encapsulating the microspheres in macrocapsules. With respect to claim 130, Soon-Shiong teaches polymerizable alginate, water-soluble poly(alkylene glycol), poly(amino acids), polysaccharides and proteins. An accelerator to increase the rate of polymerization is taught in column 10, lines 36-48. With respect to claim 131, Soon-Shiong et al do not teach PEG tetraacrylate. However, the claim, as written, does not limit the macromer to being PEG tetraacrylate, it merely states that the PEG in the Markush group is PEG tetraacrylate. With respect to

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claim 132 or 133, the claims, as written, do not limit the method of claim 3 to selection of polysaccharides or proteins from the Markush group set forth.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 166 and 129-135, 137 and 138 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-58 of U.S. Patent No. 6,258,870. Although the conflicting claims are not identical, they are not patentably distinct from each other because the biological cells recited in the claims of US '914 include islet cells (see claim 15) and cells first encapsulated in microcapsules (see claim 50).

The patent number "6,253,870" on page 1, last paragraph, of the terminal disclaimer filed 10/26/2005 is incorrect.

### ***Conclusion***

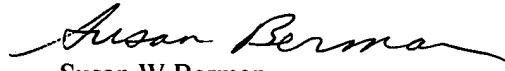
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan W. Berman whose telephone number is 571 272 1067. The examiner can normally be reached on M-F 9:30-6:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on 571 272 1078. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SB  
5/12/06

  
Susan W Berman  
Primary Examiner  
Art Unit 1711